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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/494,585	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-10,14,19,20,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-10,14,19,20,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *082703, 070703*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 1, 2, 4, 14, 28 and 29 have been amended and claim 21 is canceled as requested in the amendment of paper filed 02 December 2003. Claims 1-2, 4-5, 7-10, 14, 19-20 and 28-29 are pending and under examination in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 02 December 2003 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 101

Claims 1-2, 4-5, 7-10, 14, 19-20, 28-29 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record in paper #12 , 17 and in the action dated 02 June 2003.

Applicant argues at page 6 of the response that the Examiner never refutes that "FGF-CX" is a growth factor, and that the specification "details

stimulation of epithelial cells (including keratinocytes and fibroblasts), glial cells, and cells found in the lining of the gastrointestinal tract". Applicant further asserts that a listing of multiple utilities in the specification does not mean that there is a lack of a specific, substantial and credible utility.

The Examiner respectfully disagrees with Applicant's arguments. The claimed invention clearly has amino acid sequence similarity to the FGF protein family, and therefore, is more likely than not an FGF protein. However, FGF proteins have a variety of activities based on location of expression and the receptors to which the protein binds. These activities cannot be predicted by amino acid sequence similarity alone, and further experimentation is required to determine what activity is possessed by the newly discovered FGF protein of the instant invention. There is no evidence of record that all FGF proteins are involved in any of the asserted utilities, nor that FGF-CX is involved in any of them, nor that a person of skill in the art would have appreciated that the identification of FGF-CX as an FGF protein, without more, would have suggested any specific patentable utility.

Applicant cites *In re Gottlieb* (140 USPQ 665) and states that the Court held that one specific utility was sufficient to meet the utility requirement. However, the facts of *Gottlieb* are different from the facts of the instant application. In *Gottlieb*, the specification contained evidence that the compound being claimed had anti-fungal activity as well as all three disclosed utilities being related to this biological activity. In the instant application, the specification contains no evidence of a particular biological activity and the asserted uses do

not refer to a common biological activity; i.e. each specific asserted utility would need to be tested to confirm which asserted utility the claimed invention could be used for.

The instant specification asserts that the "FGF-CX" protein of the instant application could be used in a method of diagnosing a tissue proliferation-associated disorder, "such as tumors, restenosis, psoriasis, diabetic and post-surgery complications, and rheumatoid arthritis" (see page 4, lines 26-28 of the specification), in a method of "treating or preventing or delaying a tissue proliferation-associated disorder" (page 5, lines 28-29 of the specification) by administration of a FGF-CX nucleic acid, polypeptide or antibody, wherein the disorder includes tumors, restenosis, psoriasis, Dupuytren's contracture, diabetic complications, Kaposi sarcoma, and rheumatoid arthritis (see page 6, lines 6-7 of the specification), in a method of treating or diagnosing glia-associated disorders, including "cerebral lesions, cerebral edema, senile dementia, Alzheimer's disease, diabetic neuropathies, etc." (see page 58, lines 2-4), stimulating fibroblasts, megakaryocytes, hematopoietic cells, immune system cells, vascular smooth muscle cells treating bone fractures and osteoporosis, diagnosis and treatment of cerebral tumors (see page 58, lines 11-16). The fact that the specification also includes a recitation that the claimed invention may also stimulate cells of the gastrointestinal tract in addition to all of the other possible uses of the claimed invention does not appear to provide a substantial utility for the claimed invention as filed. A substantial utility is a utility that defines a "real world use". Utilities that require or constitute carrying out further research to

identify or reasonably confirm a "real world"context of use are not substantial utilities. In the instant situation, the specification lists numerous uses for the claimed invention which are not linked by tissue type or mechanism of action; i.e. if the invention works for one of the asserted uses, then the skilled artisan would have a reasonable expectation that it would work for the other asserted uses. Therefore, the skilled artisan would need to carry out further research on the claimed invention to determine which of the possible asserted uses the claimed invention could be used for; this does not constitute a disclosure of a substantial utility.

Applicant refers to In re Brana m 51 /f,3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), and states "the Court stated that a declaration can be used to substantiate the asserted utility since the declaration pertains to a statement already in the specification". This is not really the issue in the Brana case, but rather that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The specification disclosed that the claimed compounds had higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442. The instant application is distinguished from that of Brana in the fact

that the instant specification contains no evidence of a particular biological activity to support any of the asserted, divergent utilities.

Applicant again refers to Gottlieb at pages 7-8 of the response, as well as the Jeffers et al. reference, LaRochelle Declaration and the Press Release. However, since the instant specification fails to disclose a specific, substantial and credible utility for the claimed invention at the time the application was filed, this evidence is not persuasive to overcome the rejection.

Applicant additionally argues at page 8 of the response that "utility is properly supported by the structural similarity of this FGF-CX with other known members of the FGF family". This argument is not persuasive and has been addressed previously. As illustrated by Galzie et al., the FGF family does not share the same specific, substantial and credible utility since they have distinct biological activities which cannot be predicted from their amino acid structure. Applicant asserts that the claimed protein has a biological activity similar to a structurally related protein (FGF-9), however, these two proteins do not have the same utility since FGF-9 stimulates glial cells and the claimed protein does not. The ability of an FGF protein to stimulate endothelial cells is not a specific utility because the FGF proteins are specific for particular endothelial cells. For example, KGF stimulates keratinocytes but not fibroblasts, therefore, it cannot be used in the same way as an FGF which stimulates fibroblasts. bFGF stimulates fibroblasts and FGF-9 stimulates glial cells, and therefore, they cannot be used for the same purpose. The members of the FGF family have divergent activities in that they typically stimulate particular cell types or act on particular tissues and

they are not predictive of one another. Assignment to the FGF family is not predictive of a utility of stimulating cells of the GI tract because this is but one tissue of endothelial cell origin for which the FGF proteins are known to stimulate and the skilled artisan would need to carry out further research on the claimed invention to identify or reasonably confirm which tissue the claimed invention would stimulate.

Applicant cites In re Jolles and In re Brana in support of a finding of utility in the instant application. Brana has been discussed above and the instant case is distinguished as presented above. In In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), pharmaceutical compositions were claimed that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and doxorubicin, both of which were "well recognized in the art as valuable for use in cancer chemotherapy." Id., 206 USPQ at 887. the applicant also submitted declaratory evidence showing that eight of the claimed compositions were effective in treating tumors in a mouse model, and one was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the data derived from the mouse model were "relevant to the treatment of humans and [were] not to be disregarded," id. at 1327, 206 UPSQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. See id. at 1327-28, 206 USPQ at 891. The instant case is distinguished from that of Jolles in that the structural similarity of the claimed compound to other FGF proteins does not provide for a specific, substantial and credible utility

for the reasons of record (i.e. because the members of the FGF family do not share a common biological activity which equates to a specific, substantial and credible utility in common for the family).

Applicant additionally argues that a how to use rejection cannot stand because the instant situation does not meet the criterion of being totally incapable of achieving a useful result. This argument is not persuasive. Since the instant specification fails to provide a specific, substantial and credible utility for the claimed invention, the specification clearly does not teach how to use the claimed invention.

Claim Rejections - 35 USC '112

Claims 1-2, 4-5, 7-10, 14, 19-20, 28-29 are rejected under 35 U.S.C. '112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. '101 and for the reasons of record in paper #12, 17, and in the action dated 02 June 2003.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud